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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Copy

Office Action Summary	Application No.	Applicant(s)	
	09/869,433	MURDIN ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/20* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-85* is/are pending in the application.

4a) Of the above claim(s) *44,46-50,63-78,80-82,84 and 85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45,51-62,79 and 83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *44-85* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed on 12/20/2002, paper # 10 is acknowledged. Claims 44-85 are pending in the application.

Priority

2. This application is a national stage entry of PCT/CA99/01224 12/22/1999

Which Claims Priority from Provisional Application 60114060, filed on 12/28/1998

Which Claims Priority from Provisional Application 60123967, filed on 3/12/1999

Which Claims Priority from Provisional Application 60141271, filed on 6/30/1999

Applicant's claim the benefit of U.S.Provisional Application NO: 60/114,060 filed on 12/28/1998, 60/123,967 filed on 3/12/1999 and 60/141,271 filed on 6/30/1999 under 35 U.S.C. 119(e) for domestic priority is acknowledged. However, the provisional applications, 60/114,060 filed on 12/28/1998 and 60/123,967 filed on 3/12/1999 upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 45, 51-62, 79 and 83 with respect to SEQ.ID.NO: 1 of this application. Provisional applications, 60/114,060 and 60/123,967 (ATP/ADP translocase gene) do not disclose the corresponding nucleic acid and amino acid sequence to instant application SEQ.ID.NO: 1 and 2. For example: see figure 1 at positions 248, 296, 344 etc in applications 60/114,060 and 60/123,967 are different and do not disclose in the corresponding sequence to instant application SEQ.ID.NO: 1 and 2. However, Provisional application 60/141,271 filed on 6/30/1999 does disclose the sequences corresponding to this application and provide adequate support under 35 U.S.C. 112 for claims 45, 51-62, 79 and 83 with respect to SEQ.ID.NO: 1. Therefore, the priority is accorded as of on 6/30/1999.

Drawings

3. The drawings are objected to by the draftsperson under 37 C.F.R. 1.84 or 1.152. See PTO-948 for details.

Information Disclosure Statement

4. Information Disclosure Statement filed on 10/16/01 (Paper # 4) is acknowledged and a signed copy is attached to this Office action.

Election

5. Applicant's election of Group I, claims 44-62, 79 and 83 drawn to DNA with respect to SEQ.ID.NO: 1 in Paper # 10 (12/20/02) with traverse is acknowledged. Since applicant elected an invention, which is drawn to nucleic acid, SEQ.ID.NO: 1. Claims 45, 51-62, 79 and 83 with respect to SEQ.ID.NO: 1 are under examination.

Applicant requests the Examiner to reconsider the restriction and withdraw the restriction requirement and examine Groups I, II, IV and V, claims 44-68, 70-79, 83-85 and 80-82 in the application.

Applicants' arguments filed on 12/20/02 have been fully considered but they are not deemed to be persuasive.

Applicant states that groups I-V are linked by the common generic special technical feature as defined by PCT Rule 13.2 (37CFR1.475(a)) and therefore all the claims with respect to SEQ.ID.NO: 1 and 2 should be examined. It is the position of the Office that the expression special technical features shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. However, Kalman et al, (Accession number AE001619, 12/1/98; reference A 58 on PTOL-1449). Disclose i.e., a nucleic acid molecule comprising SEQ.ID.NO: 1, hence it does not constitute a special technical feature by definition. Therefore, lack of unity is present.

Concerning the burden of search, classification of subject matter is merely one indication of the burdensome nature of the search involved. The DNA database searches required by each of the sequences and the literature searches for each of the sequences, both of which are particularly relevant in this art, are not co-extensive and are much more important in evaluating the burden of search. For example, search and examination issues for nucleic acid vaccines are different and would not encompass protein vaccines. Further, it is doubted that applicants would readily accept the rejection of one sequence by the application of art teaching another sequence. Clearly different searches and issues are involved in the examination of each group.

The requirement is still deemed proper and is therefore made FINAL.

6. Claims 45, 51-62, 79 and 83 with respect to SEQ.ID.NO: 1 are under examination. Claims 44, 46-50 are withdrawn from elected Group I invention, as the claims are not drawn to an elected invention, SEQ.ID.NO: 1. Applicants indicate that with respect to the election, they elect SEQ ID NO: 1 and 2. It is specifically noted, that a species election was not imposed. Each of the recited sequences is deemed patentably distinct from each other and applicants were required to elect a single product for examination on the merits. As such, examination of the single product will be restricted to the nucleic acid of SEQ ID NO: 1. Claim 83 is being examined although it depends from claim 50, which is withdrawn by the Examiner.

7. Claims 63-78, 80-82, 84 and 85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 10.

Specification - Informalities

8. Claims should begin with "I claim" or "'We claim" or "What is claimed is".

Page 7, lines28- 29 refer to worldwide web address. The worldwide web address can be readily changed with rapidly changing technology and therefore, may not be available to the public. Therefore, applicant is advised to amend the specification and use some other means to recite the genome sequence. Appropriate correction is required.

On page 22, line 5, ATCC address is not the current address (see paragraph # 12 for current address). Appropriate correction is required.

Applicant's attention is drawn to pages 7a and 8. It appears that there is no coherence between page 7a, line 3 and page 8, line 1.

Abstract is not present in the application. Applicant is advised to submit the abstract of the claimed invention.

Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

9. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 45, 51-62, 79 and 83 with respect to SEQ.ID.NO: 1 are provisionally rejected

under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 31-71 especially claims 35-53, 59, 72 and 74-76 drawn to DNA of copending Application No. 09/892851. Although the conflicting claims are not identical, they are not patentably distinct from each other because in both applications applicant is claiming a nucleic acid molecule SEQ.ID.NO: 1, vaccine and pharmaceutical composition comprising SEQ.ID.NO: 1 and nucleic acid probes comprising SEQ.ID.NO: 1 and a method of preventing Chlamydia infection.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows: Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 45 is rejected under 35 U.S.C101 because the claimed invention is directed to non-statutory subject matter. The product, a nucleic acid molecule as claimed, has the same characteristics as that found in nature because the nucleic acid molecules (DNA) can be obtained from Chlamydia infected patients. To overcome this rejection the Examiner suggests the amendment of the claims to include purity limitations, which would distinguish the characteristics and utility of applicant's product as enabled in the specification from the utility of the product as it exists in nature. It is further suggested that such limitation include the terminology " purified and isolated" (i.e. if such purity is supported in the specification) and/or a description of what applicant's protein is "free of" relative to the natural source, which imparts a distinct utility to the claimed product. For relevant case law see Farbenfabriken of Elberfeld Co. v. Kuehmsted, 171 Fed. 887, 890 (N.D. Ill. 1909) (text of claim at 889); Parke-Davis & Co. v.

H.D. Mulford Co., 189 Fed. 95, 103, 106, 965 (S.D.N.Y. 1911) (claim 1); and In re Bergstrom, 427 F.2d 1394, 1398, 1401-1402 (CCPA 1970).

Claim Rejections - 35 USC 112, first paragraph

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 83 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete information how to make the plasmid pCA1764. The specification teaches general description of amplifying the amino acid ATP/ADP translocase coding gene and making an expression vector. However, it fails to teach that the specific Chlamydia nucleic acid sequence SEQ.ID.NO: 1 that encodes the SEQ.ID.NO: 2 has been cloned as an expression plasmid pCA1764. In the absence of such a disclosure, the deposit of the expression plasmid pCA1764 is required. It is not clear that the expression plasmid pCA1764 are known and publicly available or can be reproducibly isolated from nature without undue experimentation.

Because one skilled in the art could not be assured of the ability to practice the invention as claimed in the absence of the availability of the expression plasmid pCA1764of the invention, a suitable deposit for patent purposes, evidence of public availability of the expression plasmid

pCA1764 of the invention or evidence of the reproducibility without undue experimentation of the expression plasmid pCA1764 is required.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository is required. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of deposit and the complete name and full street address of the depository is required. As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the depository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of a biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;

2) The name and address of the depositor;

3) The date of deposit;

4) The identity of the deposit and the accession number given by the depository;

5) The date of the viability test;

6) The procedures used to obtain a sample if the test is not done by the depository; and

7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the expression plasmid pCA1764 described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing of a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the

biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR1.801-1.809 for further information concerning deposit practice.
The ATCC's address, effective March, 23,1998 is
AMERICAN TYPE CULTURE COLLECTION
10801 UNIVERSITY BOULEVARD
MANASSAS, VA 20110-2209

14. Claims 45, 51-62 , 79 and 83 are rejected under 35 U.5.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is referred to the interim guidelines on written description published June 15, 1998 in the Federal Register at Volume 63, Number 114, pp 32639-32645 (also available at www.uspto.gov). This is a written description rejection.

The specification also broadly describes a gene specifically by a polynucleotide sequence of SEQ ID NO: 1. The specification broadly describes as part of the invention isolated polynucleotides encoding the polypeptide of SEQ ID NO: 2, which is a "putative 98kD outer membrane protein". Applicants broadly describe the invention as (a) a nucleotide sequence or vaccine or pharmaceutical composition comprising at least 38 or 60 consecutive nucleotides, (b) a sequence which encodes a polypeptide which is at least 75% or 80% identical to the polypeptide encoded by SEQ.ID.NO: 1, said peptides which have been modified without loss of immunogenicity (c) nucleic acid sequence which encodes the immunogenic fragments comprising at least 12 consecutive amino acids of SEQ ID NO: 2, said fragments which have

been modified without loss of immunogenicity (d) nucleic acid encoding a fusion protein (i.e., a second polypeptide having adjuvant activity or a second nucleic acid encoding additional Chlamydia polypeptide). Applicants broadly describe the invention as embracing any nucleic acid molecule substitution, insertion or deletion change of nucleotides throughout the entire stretch of nucleotides found in the encoding or reference sequence by use of language in which a specified percent of amino acids can be changed in the polypeptide. As depending from these are the vectors, host cells, vaccines, pharmaceutical compositions and methods of preventing infection. The-claims encompass polynucleotide sequences comprising SEQ ID NO: 1, sequences that have a recited degree of change as compared to a reference nucleic acid sequence encoding SEQ ID N0: 2, as compared to a sequence which encodes a polypeptide encoded by SEQ ID NO: 1, complements or anti-sense sequences, immunogenic homologs that correspond to sequences from other species, mutated sequences, allelic variants and comprising nucleic acids of SEQ ID NO--1 or nucleic acids encoding SEQ ID NO: 2. None of these sequences meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that (he or she] invented what is claimed." (See Vas-Cath at page 1116.).

The specification only discloses a polynucleotide sequence consisting of SEQ ID NO: 1 which corresponds to the polynucleic acid sequence encoding the Chlamydia pneumoniae species of the protein which comprises SEQ ID N0: 2. An isolated polynucleotide comprising a nucleotide sequence encoding SEQ ID NO: 2 is also described by way of the written description

in view of the art established principle of wobble variants of triplet codons for particular bacterial amino acids as described in basic Microbiology textbooks. Thus, an isolated polynucleotide sequence comprising of SEQ ID NO: 1 meets the written description provision of 35 U.S.C. 112, first paragraph for the reasons set forth below.

The specification fails to teach a single variant or homolog of a polypeptide sequence of encoded by SEQ ID NO: 1 and it is noted that the claimed polynucleotides do not exist as an invention independent of their function in encoding a putative outer membrane protein. The actual structure or other relevant identifying characteristics of each nucleic acid that encodes a variant protein (i.e. homolog) having the claimed properties of the putative 98 kD protein can only be determined empirically by actually making every nucleic acid that encodes the recited variability (i.e. the instant 75% identity) and testing each to determine whether it encodes a protein having the particularly disclosed properties of an 98kDprotein. As noted in the Guidelines at Section I.A (2). There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonable predict the complete structure of the claimed invention from its function. There is no written description support for a method of preventing Chlamydial infection as claimed.

Applicants propose that the skilled artisan is to modify a known nucleic acid sequence encoding a known protein sequence and that modification would still describe applicant's invention as a 98kDprotein as disclosed. The 98kD outer membrane protein is uncharacterized by this specification and is not asserted to belong to any known family of proteins. The protein has specific biological properties dictated by the structure of the protein and the corresponding structure of the structural gene sequence which encodes it. There must be some nexus

between the structure of a gene sequences and the structure of the proteins encoded, and the function of that encoded proteins. However, similar function cannot be predicted from the modification of the structure of the gene or in this case the gene encoding the protein. Applicants have not shown that, by modifying a reference sequence encoding a reference polypeptide as claimed, will automatically predict the production of a 98kDouter membrane protein as disclosed. While it is true that, due to the nature of codon degeneracy, applicant may take a reference sequence and modify that sequence to be a different nucleic acid sequence, yet still have that nucleic acid encode the same putative 98 kD protein, the specification fails to teach the structure or relevant identifying characteristics of a representative number of species of a representative number of polynucleotides encoding a representative number 98kDpolypeptides, sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed. With the exception of an isolated polynucleotide comprising SEQ ID NO: 1 and an isolated polynucleotide comprising of a nucleotide sequence encoding SEQ ID NO: 2, fragments thereof and associated, vectors, vaccines, fusions etc dependent thereon, the skilled artisan cannot envision the contemplated nucleotide sequences by the detailed chemical structure of the claimed polynucleotides and therefore conception cannot be not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 U5PQ2d 1601, 1606 (CAFC 1993) and Amgen Inc V Chuaai Pharmaceutical Co Ltd., 18 U5PQ2d 1016. One cannot describe what one has not conceived. See Fiddes v. Baird, 30 U5PQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class.

15. Claims 45, 51-62, 79 and 83 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid consisting of a nucleic acid sequence as set forth in SEQ.ID.NO: 1 or polypeptide encoded by SEQ.ID.NO: 1or a vaccine or a pharmaceutical composition comprising a vaccine vector and at least a nucleic acid (i.e., pCA1764) does not reasonably provide enablement for

(a) a nucleotide sequence or vaccine or pharmaceutical composition comprising at least 38 or 60 consecutive nucleotides, (b) a sequence which encodes a polypeptide which is at least 75% or 80% identical to the polypeptide encoded by SEQ.ID.NO: 1, said peptides which have been modified without loss of immunogenicity (c) nucleic acid sequence which encodes the immunogenic fragments comprising at least 12 consecutive amino acids of SEQ ID NO: 2, said fragments which have been modified without loss of immunogenicity (d) nucleic acid encoding a fusion protein (i.e., a second polypeptide having adjuvant activity or a second nucleic acid encoding additional Chlamydia polypeptide). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Scope of enablement requires that the specification teach those in the art how to make and use the invention commensurate with the scope of the claimed invention without undue experimentation and includes an analysis of: (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The specification is not enabling for the claimed invention because the specification does not provide sufficient guidance as to how an artisan would have made all the polynucleotide sequences, vectors, and host cells expressing the polynucleotide sequences as

claimed above and would have used those without undue experimentation because the state of the prior art in the field of C.pneumoniae ATP/ADP translocase coding gene is not known. Further, the amino acid sequence encoding the C.pneumoniae ATP/ADP translocase-coding gene with respect to virulence and/or protection is also not known.

It is noted that the specification, in pages 48-51 provides description of an expression vector containing the C.pneumoniae gene, i.e. pCA1764 and immunization of mice to achieve protection against an intranasal challenge of C.pneumoniae. However, the specification fails to teach a vaccine composition comprising vaccine vector that comprises a nucleic acid sequence (by sequence identifier number) that encodes the polypeptide SEQ.ID.NO: 2 or immunogenic fragments comprising at least 12 consecutive amino acids or polypeptides with 75% identity to SEQ.ID.NO: 2. The use of the plasmid name in the Examples does not convey which sequence was used.

The specification does not provide how would an artisan have made the vaccine vector that comprises innumerable polynucleotide that encode the fragments comprising at least 12 consecutive amino acids and modified polypeptides with 75% identical to amino acid sequence to the corresponding polypeptide of SEQ.ID.NO: 2 or fragments of SEQ.ID.NO: 2. Even if one had to assume that using various molecular biology techniques described in the specification in pages 18-21, an artisan would have been able to make these polynucleotides, would all the polypeptides encoded by the isolated polynucleotides have had any specific function with respect to virulence and/or protection against C.pneumoniae is questionable. Additionally, in the absence of any function, what would have been the use of making all these polynucleotide, expression systems comprising these polynucleotide segments, host cells comprising these polynucleotide expression systems, producing the polypeptides encoded by these polynucleotides? Furthermore, just because the claimed polypeptides have amino acid identity

to a known protein (although, the extent of identity to known myosin proteins is not disclosed in the specifications), does not ensure that the polypeptide or its derived or cloned fragments would have the same function or even any function as that of the said known protein. The specification does not provide any guidance as to how an artisan would have determined what would have been the function of all these polynucleotides and how would this multitude of polynucleotide have been used as vaccine or pharmaceutical compositions.

It is concluded that the specification as filed is not enabling for the claimed invention as filed and an artisan would not have been able to practice the invention without undue experimentation. Therefore, limitation of the scope of the invention to an isolated nucleic acid molecule as set forth in SEQ.ID.NO: 1, a vaccine or pharmaceutical composition comprising the plasmid vector pCA1764 and a method of preventing or treating Chlamydia infection is proper.

Claim Rejections - 35 USC 112, second paragraph.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

17. Claims 45, 51-62, 79 and 83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45, 51, 52 and 79are indefinite because the claim recites a sequence which encodes a polypeptide encoded by SEQ ID NO: 1, however SEQ ID NO: 1 has many reading frames, each encoding its own distinct polypeptide. Therefore, the metes and bounds of the claimed nucleic acid is unclear.

Claims 51 and 52 are vague and indefinite for the recitation of "at least one first nucleic acid", "each first nucleic acid" and "second polypeptide". It is not clear what are the metes and bounds of at least one first nucleic acid, each first nucleic acid and a second polypeptide.

Claims 51 and 52 are vague and indefinite for the recitation of "vaccine vector and at least one first nucleotide molecule." Does this vaccine vector contain the polynucleotide sequence? Or does it contain a vector and a polynucleotide sequence as two components?

Claim 51 recites the limitation " each first nucleic acid " in line 18. There is insufficient antecedent basis for this limitation in the claim.

Claim 52 recites the limitation " each first nucleic acid " in line 18. There is insufficient antecedent basis for this limitation in the claim.

Claim 57 is vague in reciting "additional Chlamydia polypeptide". It is not clear what are the metes and bounds of additional Chlamydia polypeptide.

Claim 59 is vague and confusing because it recites " a pharmaceutical composition comprising a vaccine". Vaccines and pharmaceuticals are two different things. A vaccine requires that the compound is capable of providing protective immune response whereas a pharmaceutical composition just requires some therapeutic effect. It is not clear what is being claimed? Appropriate correction is requested.

Claims 61-62 recite in the alternative "complementary or antisense sequence of said nucleic acid molecule". However, these terms have the same meaning and are redundant. Applicants are directed to amend the claim to choose one means of claiming the opposite nucleic acid strand.

Claim 83 is indefinite as it depends upon non-elected claim or subject matter. Correction is required.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 45, 51-62 are rejected under 35 U.S.C. 102(a) as being anticipated by Kalman et al. (Accession number AE001619, 'Submitted 12/1/98' & 'Nat. Genet. 1999, 21(4): 385-389, reference A 58 on PTOL-1449).

Claims are drawn to a nucleic acid and vaccine composition comprising a vector and at least one first nucleic acid and Claims are also drawn to pharmaceutical composition comprising said nucleic acid sequence as set forth in SEQ.ID.NO: 1, a probe of 5 to 100 nucleotides and a primer of 10-40 nucleotides with at least 75% similar to the nucleic acid molecule SEQ.ID.NO: 1.

Kalman et al. disclose nucleotide sequences SEQ ID NO: 1 (see the sequence alignment for a nucleotide sequence 100% including 5-100 and 10-40 nucleotides). Therefore, the prior art meets the limitations of claims. Kalman et al also disclosed that DNA was isolated and cloned in to M13 (see page 388) that encodes a polypeptide. Therefore, the prior art meets the limitations of a vector (M13) and a nucleic acid sequence that encodes a polypeptide (see the sequence alignment for a nucleotide sequence). The terms "vaccine" and "pharmaceutical composition" are intended use only. A recitation of the intended use of the claimed invention

must result in a structural difference between the claimed inventions from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and therefore would be inherent in the preparation of Kalman et al.

It is acknowledged that weight is given to every term in claims 51 and 52 This is why the instant claims 51and 52 drawn to vaccines and pharmaceutical composition are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same nucleic acid and formulations thereof as claimed.

20. Claims 61-62 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60- -- 62).

The claims are drawn to isolated nucleic acid sequences, which are probes and primers having variable lengths (5-100 nucleotides) based on SEQ ID NO: 1 or complements thereof.

Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60-62) each disclose a wide variety of probes, primers and linkers of over 10 nucleotides in length. Thus the disclosed random primers, probes and linkers anticipated the instant claims. The primers and linkers have been applied as relevant to the restriction map provided for SEQ ID NO: 1.

Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), disclose kits containing isolated packaged random 6-mer primers and random 9-mer primers. The random primer kits contain all possible 6 mer and 9 mer sequences for priming DNA sequences for labeling. The prior art anticipated the claimed invention.

21. Claims 45and 51-62 are rejected under 35 U.S.C. 102 (a) as being anticipated by Griffais R (Accession No: AAX91990, WO 9927105, published on 6/3/99).

Claims are drawn to an isolated nucleic acid and vaccine composition comprising a vector and at least one first nucleic acid and Claims are also drawn to pharmaceutical composition comprising said nucleic acid sequence as set forth in SEQ.ID.NO: 1, a probe of 5 to 100 nucleotides and a primer of 10-40 nucleotides with at least 75% similar to the nucleic acid molecule 0f SEQ.ID.NO: 1.

Griffais R discloses a nucleotide sequence that is 99.8% identical to SEQ ID NO: 1 (see the sequence alignment including 5-100 and 10-40 nucleotides). Therefore, the prior art meets the limitations of claims 45, 51-62. The terms "vaccine" and "pharmaceutical composition" are intended use only. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed inventions from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. A "pharmaceutically acceptable carrier" reads on water and therefore would be inherent in the preparation of Griffais R.

It is acknowledged that weight is given to every term in claims 51 and 52 This is why the instant claims 51and 52 drawn to vaccines and pharmaceutical composition are scrutinized differently from a composition claim under 112, first paragraph. However, under prior art rejections, the term vaccine must be weighed with the structural limitations of the claim. If the vaccine merely comprises a known composition, the term carries little weight absent evidence of

structural difference. Of course, the existence of an unobvious structural difference would define over the prior art. Here, the prior art teaches the same nucleic acid and formulations thereof as claimed.

Conclusions

22. No claims are allowed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D

2/27/03

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